REMARKS

The Examiner's Office Action mailed November 27, 2009, which rejected all pending claims, has been reviewed. Reconsideration in view of the foregoing amendments and remarks is respectfully requested. Moreover, Applicants have reviewed the Office Action of November 27, 2009, and submit that the following amendments and remarks are responsive to all points raised therein. Applicants believe that currently pending claim 1 is now in form for allowance.

Status of Claims

Claims 1 and 3 are pending in the application. Claim 1 has been amended to further specify the structure of the tablet. Support for the amendment to claim 1 can be found, for example, at page 4, lines 9-17 of the specification. New claim 3 has been added. Support for new claim 3 can be found, for example, at page 1, lines 15-20; page 3, lines 16-24; page 4, lines 1-8; and the example of the specification. No new matter has been added.

Rejection of Claim 1 under 35 USC § 103(a)

Reconsideration is requested of the rejection of claim 1 under §103(a) as being unpatentable over Faour et al. (US 6004582) in view of Thombre (US Patent Application Publication 20030175326), Gennaro , 1990, and Federal Registry, 1997 (vol. 62(139) 38906-38907) as modified by Federal Registry, 1999 (vol. 64(171) 48295).

The present invention is directed to an uncoated tablet. Claim 1 requires that the uncoated tablet include from 20 to 45% by weight enrofloxacin, from 18 to 35% by weight of lactose, from 5 to 10% by weight microcrystalline cellulose, and from 5 to 20% by weight of meat flavor. New claim 3 requires the same limitations as claim 1, but further requires that the tablet include from about 10 to about 40% by weight of maize starch, from about 1.5 to about 4% by weight polyvinyl pyrrolidone, from about 0.05 to about 0.3% by weight colloidal silicon dioxide, and from about 0.4 to about 1% by weight magnesium stearate.

As stated in the MPEP Section 2111.02, "[a]ny terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation."[1]

Claim 1 and claim 3 require that the tablet be an uncoated tablet. Both the Faour and Thombre reference teach away from the present invention as they both discuss coated formulations. The Federal Registry only teaches that enrofloxacin tablets have been administered to dogs. The combination of these references, may guide someone skilled in the art to develop a coated tablet with enrofloxacin that includes lactose and microcrystalline cellulose, but this would be substantially different than the tablet of the present invention.

Nevertheless, the Applicants also provide the following additional argumentation. It is generally known that palatability of drugs can be increased by adding suitable aromas and/or flavoring. Thombre is one example used by the Examiner, however, others have used meat flavoring as well. It is also generally known that these substances frequently impair the mechanical properties of a tablet to a degree which is unacceptable in practice. To overcome such disadvantages the choice of optimal ingredients as well as the choice of each ingredient's concentration is important.

The unexpected properties of the present invention is that by choosing the appropriate ingredients with the appropriate concentrations a tablet containing enrofloxacin and meat flavor are made having acceptable mechanical properties. This can be evidenced by the attached data and declaration by Dr. Kanikanti. In this experiment a tablet of the present invention (Batch no. 1164) was compared to a tablet having standard ingredients (exchange of microcrystalline cellulose and lactose for maize starch – Batch no. 1165) for its crushing strength and friability at different compression forces. Please see attachment A for a description of the composition of the tablets tested, manufacturing process, and a description of the determination of the crushing strength of the tablets. The tablet of the present invention has considerably higher crushing strength and lower

[1] See Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989); Pac-Tec Inc. v. Amerace Corp., 903 F.2d 796, 801, 14 USPQ2d 1871, 1876.

friability than the maize starch only tablet. The tablets were tested according to the USP friability test which is used to determine the abrasion resistance (=friability) of the tablets. The abrasion is required to be below 1% by the United States Pharmacopiea (See USP 23, page 1981, attached herewith for testing method and range). For the tablet of the present invention, no abrasion was detected. For the maize tablets made with a compression force of 10 to 20 kN, they broke in the abrasion test. For the maize tablets made with 30 kN, they had an abrasion of 7.66%, which is unacceptable (higher than 1% allowed). As Dr. Kanikanti stated in his declaration, the significant difference between crushing strength and friability is not anticipated based on changing maize starch, a common filler, to microcrystalline cellulose and lactose. It is surprising that the present formulation, combination of microcrystalline cellulose and lactose, made the tablet perform so well.

As such, Applicant submit that claim 1 is patentable over Faour et al. in view of Thombre, Gennaro, and Federal Registry, 1997 as modified by Federal Registry, 1999. Similarly, Applicants submit that new claim 3 is also patentable over the references cited by the Examiner.

Conclusion

Applicants respectfully submit that the pending claims are now in form for allowance.

The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment in connection with this amendment to Deposit Account No. 50-4260.

Respectfully submitted,

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Attachment A

The composition of the two formulations is as follows:

	1164 (% w/w)	**1165** (% w/w)
Enrofloxacin	20	20
Lactose monohydrate	----	35
Microcrystalline cellulose	-------	10
Maize starch	52	7
Povidone 25	5	5
Artificial beef flavor	20	20
Colloidal silicon dioxide	2.0	2.0
Magnesium stearate	1.0	1.0

The ingredients are mixed well and passed through a 1 mm screen manually and then compressed into tablets weighing 750 mg using tools of oblong shape (18 mm length and 8 mm width with one score). The compression force was varied as shown in the diagram attached. The samples collected at each compression were tested for tablet hardness and friability as described by the USP.

Determination of the crushing strength:
The tablets are placed between the jaws of the hardness tester (Machine type: Schleuniger 6D hardness tester) in such a way that the tip of the capsule shape will be in contact with the jaws when the jaws move. The force in Newtons required to crush the tablets is noted. This is a routine procedure done by the skilled person in the art for determining the tablet hardness with Schleuniger hardness tester.